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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,341	06/09/2006	Sung Youb Jung	430156.401USPC	7156

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 5400
SEATTLE, WA 98104

EXAMINER
DAHLE, CHUN WU

ART UNIT	PAPER NUMBER
1644	

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06/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/535,341	**Applicant(s)** JUNG ET AL.	
	Examiner CHUN DAHLE	**Art Unit** 1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 May 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-7,13 and 14*.
   Claim(s) withdrawn from consideration: *8-12*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Maher M. Haddad/
Primary Examiner, Art Unit 1644

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments have not been found persuasive to overcome the rejections of record for following reasons:

Claims 1, 2, 7, 13, and newly added claim 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Maddon et al. (US Patent 6,034,223) for reasons of record.

Applicant's arguments have been fully considered but have not been found persuasive.
Applicant argues that the prior art teaches CD4 and Fc fusion protein linked to non-peptide toxin. Applicant asserts that the claimed invention is drawn to an Fc fragment as a drug carrier wherein the Fc is not fused by conventional recombinant methods. Applicant further argues that newly added claim 14 recites "An Fc fragment as a drug carrier …. consisting essentially of the Fc fragment covalently linked to a drug through a non-peptide linker". Applicant asserts that the prior art CD4-fc fusion does not anticipate the claimed Fc structure because CD4 would materially affect the characteristics of the Fc fragment. Thus, applicant asserts that the prior art teachings do not anticipate the claimed invention.

This is not found persuasive for following reasons:

In contrast to applicant's assertion, it is noted that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In this case, the claims are drawn to an Fc fragment covalently lined to a drug through a non-peptide linker. Maddon et al. teach a human Fc region chemically linked to non-peptide toxins via site-specific linkage through the N-linked sugar residues present on the Fc region. Thus, Maddon's Fc region would read onto the instant claims.

Regarding the newly added claim 14, contrary to applicant's reliance on "consisting essentially of" to exclude the prior art's CD4, it is noted that the instant specification defines the claimed "drug" as any proteins listed on pages 29-31 including CD4. Thus, the prior art species of CD4 would anticipate the claimed genus of "drug" even though the instant claims recites the transitional phrase of "consisting essentially of".

Therefore, applicant's arguments have not been found persuasive.

Claims 1-7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maddon et al. (US Patent 6,034,223) in view of Presta (US Patent 6,737,056).

Applicant's arguments have been fully considered but have not been found persuasive.
Applicant's arguments and the Examiner's rebuttal regarding the teachings of Maddon et al. are essentially the same as discussed above.

Applicant further argues that the references do not teach or suggest or motivate one of skill in the art to arrive at the claimed features. Applicant asserts that Presta does not teach an Fc fragment covalently linked to a drug through non-peptide linker. Thus, applicant argues the rejection should be withdrawn.

This is not found persuasive for following reasons:

In response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combination of references. See MPEP 2145. Further, contrary to applicant's arguments that no specific suggestion or teaching in the references to combine prior art, it is noted that KSR forecloses the argument that a specific TSM is required to support the finding of obviousness. Here, it is obvious to one of skill in the art at the time of the invention to substitute the human IgG2 Fc region that does not bind Fcγs and have less effector function taught by Maddon et al. with the aglycosylated human IgG4 Fc region taught by Presta since human IgG4 Fc region can be engineered to have reduce binding to Fcγs and decreased effector function. The substitution would have yielded predictable results of an aglycosylated human IgG4 Fc region that is covalently lined to a drug via non-peptide linker.

Therefore, applicant's arguments have not been found persuasive.